REMARKS

Claims 6-21 and 24 have been cancelled. Accordingly, the remarks below only address the Office's rejections to claims 1-5, 22, 23, and 25-30, which are presently pending.[1]

I. 35 U.S.C. 103(a) Rejection

Reconsideration is requested of the rejection of claims 1-5, 22, 23, and 25-30 under 35 U.S.C. §103(a) in view of Senn-Bilfinger[2], Ruwart[3], and Lindberg et al.[4]

Claim 1 is directed to a method to treat a **viral infection** in a subject. The method involves administering a sulfur-containing (H^+/K^+) ATPase inhibitor to the subject.

Senn-Bilfinger disclose a class of substituted benzimidazoles all having a trifluoromethyl substituent on a benzene ring and a methoxy substituent on a pyridine ring.[5] They disclose that the primary utility for their compounds is to **inhibit gastric acid secretions**. Moreover, Senn-Bilfinger also disclose that because the compounds inhibit gastric acid secretions, that they are effective in treating illnesses which are diseases of the stomach and intestine, such as gastric ulcers, duodenal ulcers, or gastritis resulting from gastric acid secretions.[6]

Ruwart disclose the use of heterocyclylalkylsulfinylbenzimidazoles for the treatment or prevention of **gastrointestinal inflammatory diseases**, such as gastric ulcers, duodenal ulcers, and intestinal inflammatory disease.[7] Moreover, according to Ruwart, heterocyclylalkylsulfinylbenzimidazoles are effective in preventing

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[1]U.S. Patent No. 5,945,425 is in part directed toward the subject matter of claims 6-21 and 24. As such, these claims have already been found patent able over all the cited art detailed in Paper 3. Applicants, therefore, have not addressed the Office's 35 U.S.C. 103 rejection of claims 6-21 and 24 as detailed in Paper 3.

[2] Senn-Bilfinger, U.S. Patent No. 4,472,409.

[3]Ruwart, U.S. Patent No. 4,359,465.

[4]Lindberg et al., (1987) TIPS 8:399-402.

[5]See Senn-Bilfinger, at column 1, lines 53-60.

[6]See Senn-Bilfinger, at column 11, lines 35-65; also see column 14 detailing the examples where the compounds ability to prevent gastric ulcers is attributed to their ability to inhibit gastric secretions.

[7]See Ruwart, at column 1, lines 5-10.

gastrointestinal inflammatory diseases at the dosages they administer because of their **anti-inflammatory properties.**[8]

Unlike the cited art, the method of claim 1 is **not** the provision of a compound or method to **treat gastric ulcers, duodenal ulcers or gastritis** resulting from either excessive gastric acid secretion, as disclosed in Senn-Bilfinger, or resulting from an inflammatory response, as disclosed in Ruwart. Rather, claim 1 is the provision of a method to treat a **viral infection** by administering a sulfur containing compound that inhibits a (H^+/K^+) ATPase.

According to the Office, however, it would have been obvious to use the sulfur containing compounds disclosed by Senn-Bilfinger as antiviral agents because Ruwart is said to disclose that compounds "structurally similar" to those required by claim 1 and disclosed by Senn-Bilfinger, **"can be used for antiviral agents."**[9] This is not correct. While Ruwart disclose that an **inflammatory response**[10] may be **caused** by a wide variety of agents present in the gastrointestinal tract, including microorganisms such as viruses and fungi, nowhere do they disclose that their compounds, the compounds disclosed by Senn-Bilfinger, or the sulfur-containing (H^+/K^+) ATPase inhibitors required by claim 1, would be effective for the **treatment of viral infections**.[11] Claim 1 is not directed to causes of inflammatory responses or to methods of treating inflammatory responses. Instead, claim 1 is directed toward a method for the treatment of **viral infections** by administering a sulfur containing compound that inhibits a (H^+/K^+) ATPase. Moreover, the fact that microorganisms may trigger an inflammatory response, as disclosed by Ruwart, is well known in the art and would not have led a skilled artisan to select a sulfur containing compound that inhibits a (H^+/K^+) ATPase for the treatment of viral infections, as required by claim 1, without the disclosure of the Applicants' patent application.

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[8]See Ruwart, at column 8, lines 35-45 where it is disclosed administration of the compounds results in "total prevention of the inflammatory process."

[9]See Paper 3 at page 3.

[10]See Ruwart, at column 1, lines 40-45, where the inflammatory response is described as the formation of edema, the presence of characteristic cells such as leucocytes, histiocytes and macrophages, and in some cases, necrosis and ulceration of the surface epithelium.

[11]See Ruwart, at column 1, lines 45-50, where it is disclosed that "these inflammatory diseases are known to be caused by a wide variety of agents present in the gastrointestinal tract,...such agents include microorganisms (viruses and fungi)."

The defect in the Office's obviousness rejection cannot be overcome by resort to Lindberg et al. Lindberg et al. disclose a class of gastric acid secretion inhibitors, the sulphinylbenzimidazoles, which prevent gastric acid secretion by inhibiting the gastric H^+/K^+ ATPase.[12] According to Lindberg et al. the primary use of the compounds is for the treatment of gastric ulcers.[13] Claim 1, on the other hand, is directed toward the treatment of a viral infection by the administration of a sulfur containing compound that inhibits a (H^+/K^+) ATPase. While Lindberg et al. do disclose sulfur containing H^+/K^+ ATPase inhibitors, nowhere do they disclose or suggest that these compounds would be effective for the treatment of a **viral infection**, as required by claim 1.

The Office, however, asserts that it would have been obvious to use the sulfur containing compounds disclosed by Senn-Bilfinger as H^+/K^+ ATPase inhibitors because Lindberg et al. disclose that benzimidazole compounds containing sulfur inhibit the gastric H^+/K^+ ATPase. This is not correct. While Lindberg et al. do disclose sulfur containing compounds that inhibit the gastric H^+/K^+ ATPase and Senn-Bilfinger do disclose sulfur containing compounds that inhibit gastric acid secretions, their collective disclosure does not render claim 1 obvious. The cited art, alone or in combination, does not disclose or suggest sulfur containing compounds that inhibit a (H^+/K^+) ATPase are effective for the treatment of a **viral infection**, as required by claim 1.
A skilled artisan empowered with the collective art of record, therefore, would not arrive at the method of claim 1 without the disclosure of the Applicants' patent application

For the foregoing reasons, the Office has failed to establish that claim 1 is *prima facie* obvious in view of Senn-Bilfinger, Ruwart, and Lindberg et al. Moreover, claims 2-5, 22, 23, and 25-30, which depend from claim 1, are likewise patent able over these references for the reasons stated with respect to claim 1.

Moreover, in addition to the elements of claim 1, claims 3, 22, and 23 require that the viral infection is a **DNA viral infection**. Also, in addition to the elements of claim 1, claims 4 and 25 require that the DNA viral infection is a **herpetoviridae virus infection**. Nowhere does the cited art of record, either alone or in combination, disclose or suggest administering a sulfur containing compound that inhibits a H^+/K^+ ATPase for the treatment of a DNA viral infection, as required by claims 3, 22 and 23, or for the treatment of a herpetoviridae virus, as required by claims 4 and 25.

Furthermore, in addition to the requirements of claim 1, claims 5, 26, and 27 require that the compound administered inhibits both a H^+/K^+ ATPase and a **viral**

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[12]Lindberg et al. see abstract.

[13]*Id.*

protease. Nowhere does the cited art of record, either alone or in combination, disclose or suggest administering a sulfur containing compound that inhibits both a H^+/K^+ ATPase and a viral protease for the treatment of a viral infection, as required by claims 5, 26, and 27. Moreover, in addition to the requirements of claim 1, claims 28-30 require that the viral infection is a **DNA viral infection** and that the compound administered inhibits both a H^+/K^+ ATPase and a **viral protease**. Nowhere does the cited art of record, either alone or in combination, disclose or suggest administering a sulfur containing compound that inhibits both a H^+/K^+ ATPase and a viral protease for the treatment of a DNA viral infection, as required by claims 28-30.

Unable to establish a *prima facie* case of obviousness, it appears that the Office has effectively slipped into an improper "obvious to try" analysis, informed by hindsight which Applicants' disclosure affords. But the courts have consistently held that the test for a *prima facie* case of obviousness is not whether an invention is obvious to try.[14] Instead, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to combine the references, and there must be some reasonable expectation of success. For all the reasons detailed above, the Office has not met this legal standard.

II. Non-Statutory Double Patenting Rejection

Claims 1-5, 22, 23, and 25-30 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-17 of U.S. Patent No. 5,945,425. Applicants file herewith a terminal disclaimer disclaiming the amount of any patent term on a patent issuing from this application which extends beyond the patent term of U.S. Patent No. 5,945,425 in order to obviate this rejection. Applicants, accordingly, respectfully request reconsideration and withdrawal of the non-statutory double patenting rejection.

III. Conclusion

In light of the foregoing, Applicants request withdrawal of the final rejection, entry of the claim amendments, withdrawal of the claim rejections, and solicit an allowance of the claims. The Examiner is invited to contact the undersigned attorney should any issues remain unresolved.

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[14] See In re O'Farrell, 7 U.S.P.Q.2d 1673, 1680-81 (Fed. Cir. 1988).

VERSION WITH MARKINGS TO SHOW CHANGES MADE

CLAIM 6: Canceled
CLAIM 7: Canceled
CLAIM 8: Canceled
CLAIM 9: Canceled
CLAIM 10: Canceled
CLAIM 11: Canceled
CLAIM 12: Canceled
CLAIM 13: Canceled
CLAIM 14: Canceled
CLAIM 15: Canceled
CLAIM 16: Canceled
CLAIM 17: Canceled
CLAIM 18: Canceled
CLAIM 19: Canceled
CLAIM 20: Canceled
CLAIM 21: Canceled

CLAIM 22:

22. (once amended) The method of claim [21] 3 wherein the inhibitor contains a divalent sulfur bridge.

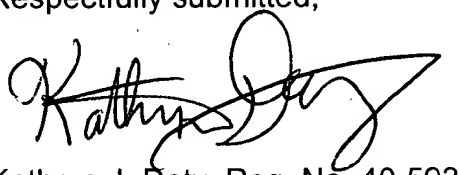
CLAIM 23:

23. (once amended) The method of claim [21] 3 wherein the inhibitor contains a sulfoxide.

CLAIM 24: Canceled

If there are any additional charges in this matter, please charge Deposit Account No. 19-1345.

Respectfully submitted,



Kathryn J. Doty, Reg. No. 40,593
SENNIGER, POWERS, LEAVITT & ROEDEL
One Metropolitan Square, 16th Floor
St. Louis, Missouri 63102
(314) 231-5400

KJD/rle
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